II. REMARKS

Claims 1-5, 12, 13, 24 and 25 are pending and were rejected under 35 U.S.C. § 112, first and second paragraphs. Applicants note with appreciation that the rejection of claim 1 as allegedly containing new matter has not been reiterated and, therefore, is considered withdrawn.

By amendment herein, claim 1 has been reformatted to clarify antecedent basis for the term "said immunogenic portion of said antigen." Claim 25 has been canceled, without prejudice or disclaimer. Entry of the foregoing amendments and consideration of the following remarks is respectfully requested.

Drawings

New corrected drawings were filed June 20, 2003 under separate cover.

35 U.S.C. § 112, First Paragraph

Claims 1-5, 12-13, and 24-25 stand rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In support of the rejection, the Examiner states:

> In response, the Examiner asserts that the claims as amended are broader in scope as they now encompass methods of generating an immune response. However, the scope of generating an immune response encompasses treatment and prevention. The claims when taken in light of the teachings of the specification are properly interpreted to read on gene therapy. It is maintained that gene therapy is an unpredictable art; the evidence of record has failed to provide guidance to overcome the unpredictability of gene therapy art with respect to the full scope of the methods as claimed ... the instant specification has failed to provide guidance which correlates methods as claimed with treatment or prevention of intracellular pathogen infection. Furthermore, the instant specification has failed to provide guidance which correlates administration of any polynucleotide which encodes any immunogenic portion of any antigen and the administration of any immunogenic portion of any antigen with generation of an immune response against an intracellular pathogen, in particular when the immune response results in treatment or prevention of intracellular pathogen infection. (Office Action, page 4).

Applicants traverse the rejection. The pending claims are drawn to methods of generating an immunological response to intracellular pathogens in warm-blooded animals. The Examiner has rejected the claims stating that "the specification has failed to provide guidance which correlates the methods as claimed with treatment or prevention of intracellular pathogen infection." The claims in no way impose the limitation of therapeutic or prophylactic responses.

The specification does teach methods of treatment, however, "a positive limitation from the specification cannot be read into a claim that does not impose that limitation." See, *e.g.*, M.P.E.P. § 2106. As explained in *In re Prater,* 415 F.2d 1393, 1404-05 (CCPA 1969):

> ...reading a claim in light of the specification to thereby interpret limitations explicitly recited in the claim, is a quite different thing from "reading a limitation of the specification into a claim," to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim.

The court in *Prater* held it was impermissible to import subject matter from the specification into the claims.

Similarly, in the present case, the Examiner is impermissibly importing a treatment or prevention limitations from the specification into methods of generating an immune response, where such a limitation is not recited. The claims are clearly directed to methods of generating an immune response and, as such, the possible effects (treatment or prevention) of the immune response and/or difficulties with gene therapy are not pertinent to the claimed subject matter.

In fact, Applicants have clearly enabled the claimed methods throughout their scope. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *Ex parte Forman,* 230 USPQ 546 (BPAI 1986). In the pending case, Applicants are in no way required to show that every immune response be therapeutic or prophylactic, or even that the immune response to each antigen (or portion thereof) be of the same nature or magnitude. All that is required is that the specification teaches a skilled practitioner how to introduce the selected antigen(s) into a selected warm-blooded animal and then examine the immunogenic effects of the antigen(s) using any number of the assays. These simple procedures and assays are clearly set forth in the specification and do not involve undue experimentation. The skilled artisan could readily select a gene delivery vehicle as claimed including an antigen in which the practitioner is presumably already interested, according to the disclosure, and test whether or not immune responses are generated in a selected warm-blooded animal, again according to the disclosure. If no immune response is generated, the selected combination of gene delivery vehicle, antigen(s) and/or warm-blooded animal does not fall within the scope of the claims.

Thus, for the reasons of record and reiterated herein, the claims as presently presented are of reasonable scope and are fully enabled by the specification as filed. Accordingly, withdrawal of this sole remaining rejection is respectfully requested.

35 U.S.C. § 112, Second Paragraph

All pending claims stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. In particular, there was alleged to be insufficient antecedent basis for the limitation "said immunogenic portion of said antigen" in step (b) of independent claim 1 (from which all other claims ultimately depend). (Office Action, page 5). Claim 25 was also rejected as for depending from a previously canceled claim. (Office Action, page 5).

The foregoing amendment to claim 1 and cancellation of claim 25, without prejudice or disclaimer, obviate these rejections. Applicants reiterate that an antigen may be "obtained from" an intracellular pathogen in any of the ways set forth in the specification, for example by recombinant production techniques, chemical synthesis, isolation, selection and/or modification of any of these proteins. (*See, e.g.*, page 16, line 15 to page 17, line 7; page 15, lines 29-30; and page 16, line 3). Applicants respectfully submit that withdrawal of the rejections under section 112, second paragraph is in order.

III. CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the claims are now in condition for allowance and request early notification to that effect.

Please direct all further communications regarding this application to:

Marcella Lillis, Esq.
CHIRON CORPORATION
Intellectual Property - R440
P.O. Box 8097
Emeryville, CA 94662-8097
Telephone: (510) 923-8406; Facsimile: (510) 655-3542

Respectfully submitted,

Date: 8 July 03

By: Pasternak
Dahna S. Pasternak
Registration No. 41,411

CHIRON CORPORATION
Intellectual Property - R440
P. O. Box 8097
Emeryville, CA 94662-8097
Tel.: (510) 923-8406
Fax: (510) 655-3542